

Message Text

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PAGE 01 STATE 106883
ORIGIN HEW-06

INFO OCT-01 ARA-14 EUR-12 EA-12 ISO-00 OES-07 MED-03
/055 R

DRAFTED BY DHEW/FDA: JRWEINROTH, MD:VB
APPROVED BY OES/ENP/EN: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EUR/WE:AHUGHES(INFO)
EUR/SE:ESMITH(INFO)
ARA/AND/E:JALLITTO(INFO)
EUR/WE:KSMITH(INFO)
EA/TIMBS:LROCKE,JR(INFO)
EA/K:FMISCH(INFO)

-----064485 270231Z /70

P 262212Z APR 78
FM SECSTATE WASHDC
TO AMEMBASSY MADRID PRIORITY
AMEMBASSY ANKARA PRIORITY
AMEMBASSY TAIPEI PRIORITY
AMEMBASSY QUITO PRIORITY
AMEMBASSY LISBON PRIORITY
AMEMBASSY BANGKOK PRIORITY
AMEMBASSY SEOUL PRIORITY

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E.O. 11652: N/A

TAGS:OGEN, ETRD, EIND, TBIO, SP, TU, TW, EC, PO, TH, KS,

SUBJECT: FDA ADVISORY - SUB POTENT ANTIBIOTIC SENSITIVITY
DISCS (RECALL D151-8)

1. FDA ADVISES OF THE FOLLOWING RECALL:
PRODUCT INVOLVED - BACTO NEOMYCIN 10 MCG., ANTIBIOTIC
SENSITIVITY DISCS FOR LABORATORY USE. PACKED 50 DISC PER
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MAGAZINE UNDER DIFCO LABORATORIES LABEL. DISTRIBUTED AS
6/50 DISC MAGAZINES PER CARTONS, OR IN ANTIBIOTIC SETS WITH
OTHER ANTIBIOTIC DISCS. DIFCO SENSITIVITY DISCS ARE
STANDARDIZED PAPER DISCS OF KNOWN ABSORPTIVE CAPACITY,
CONTAINING A SPECIFIC AMOUNT OF ANTIBIOTIC PER DISC.

2. PRODUCT IDENTIFICATION: ANTIBIOTIC SENSITIVITY DISCS

AN VIALS LABELED, "BACTO DISPENS-O-DISC NEOMYCIN 10 MCG. SENSITIVITY DISCS FOR LABORATORY USE, EXPIRE MAY 79, LOT - DIFCO LABORATORIES, DETROIT, MICHIGAN." PRODUCT IS DISTRIBUTED AS 6/50 DISC MAGAZINES IN CARTON LABELED SIMILAR TO MAGAZINE VIALS, OR IN ANTIBIOTIC SETS WITH MAGAZINE OF OTHER ANTIBIOTICS. INSTRUCTIONAL INSERT PACKED WITH THE PRODUCT.

3. ALL PRODUCT UNDER DIFCO LABEL. NO PRIVATE LABELS.

PRODUCT CODE	PRODUCT	CONTROL NUMBER
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6172-33-0	6/50 DISC MAGAZINES	630567
6172-33-0	6/50 DISC MAGAZINES	632624
6172-33-0	6/50 DISC MAGAZINES	637623

6172-33-0	BACTO - SENSITIVITY DISCS - VIALS,	631883
	NEOMYCIN 10 MCG	633671
	(6 VIALS)	637320
		638080
		638895

6012-32-5	ANTIBIOTIC SETS	630371
6012-32-5	ANTIBIOTIC SETS	631698
6012-32-5	ANTIBIOTIC SETS	633582
6012-32-5	ANTIBIOTIC SETS	634602

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6012-32-5	ANTIBIOTIC SETS	633447
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4. MANUFACTURER/RECALLING FIRM: DIFCO LABORATORIES, 920 HENRY STREET, DETROIT, MICHIGAN.

5. REASON FOR RECALL: ON NOVEMBER 30, 1977, DIFCO LABORATORIES ISSUED RECALL LETTER STATING THAT THEY HAD DETERMINED THAT THE POTENCY OF THE LOT OF NEOMYCIN SENSITIVITY DISCS INVOLVED WERE BELOW THE RANGE ESTABLISHED. CONSIGNEES WERE TO RECALL ANY UNUSED NEOMYCIN 10 MCG. VIALS OF CONTROL NUMBERS INVOLVED AND DESTROY ALL PACKAGES OF THE FIRST (5) LOT NUMBERS AND FROM THE ANTIBIOTIC SETS (KEEPING REMAINING VIALS IN SETS). CONSIGNEES WERE TO ADVISE FIRM OF QUANTITY OF VIALS DESTROYED FOR REPLACEMENT OR CREDIT.

6. POSTS REQUESTED TO DETERMINE IF CONSIGNEES ADVISED OF RECALL AND ACTION REQUIRED. ANY QUESTIONS SHOULD BE REFERRED TO DIFCO.

7. CONSIGNEES AS FOLLOWS:

FRANCISCO SORIA MELGUIZO SL ERNESTO MEDINA CUE MD
CARAMUEL 38 2620 ZAMORA
MADRID 11 SPAIN PASAY CITY, PHILIPPINES

MUHIDDIN DIZDARER RAFAEL VALDEZ AVILES
MODERN CARSI NO. 207 P O BOX 3925
ULUS ANKARA TURKEY GUAYAQUIL ECUADOR

CHENG CHIN TRADING CO. LTD. CHIEF PURCHASING/CONTROL
NO 75 SECTION 1, HANKOW ST. FOOD AND AGRICULTURAL ORGAN.
TAIPEI, TAIWAN OF THE UNITED NATIONS
-- VIA DELLO TERME CARACALLA
-- 00100 ROME ITALY

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OMNIA PRO MEDICO CANTIRA ENTERPRISES
CASILLA 575 BANGLADES LTD.
QUITO ECUADOR 51 MOTIJHEEL COMMERCIAL AREA
-- DACCA 2 BANGLADESH
ESTABELECIMENTOS BARRAL
PRACA JOSE FONTANA 4 WHITE AND COMPANY LTD.
LISBON PORTUGAL P.O. BOX 2718
-- BANGKOK, THAILAND
SAM KWANG CHEMICAL
COMMERCE CO. YUONG TAI HSING TRADING
235-20 YONGOOD DONG P.O. BOX 3445
DONGDAIMOON-KU TAIPEI TAIWAN
SEOUL 131 KOREA

OTTO NORDWALD KG CIECH
HEINRICHSTRASSE 5 JASNA 12
HAMBURG 50 GERMANY WARSAW POLAND

UNIAO FARMACEUTICA LTDA
AVE SAMORA MACHEL 202-1
CAIXA POSTAL 334
MAPUTO MOZAMBIQUE VANCE

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS, CHEMICALS
Control Number: n/a
Copy: SINGLE
Draft Date: 26 apr 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE106883
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, MD:VB
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780179-0644
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t19780413/aaaaaksh.tel
Line Count: 158
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: a6a92fa7-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 29 mar 2005
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2838341
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - SUB POTENT ANTIBIOTIC SENSITIVITY DISCS (RECALL D151-8)
TAGS: OGEN, ETRD, EIND, TBIO, SP, TU, TW, EC, PO, TH, KS
To: MADRID ANKARA MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/a6a92fa7-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
Markings: Sheryl P. Walter Declassified/Released US Department of State EO Systematic Review 20 Mar 2014